



PATENT COOPERATION TREATY

PCT/JP2005/000567

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

From the INTERNATIONAL BUREAU

To:

SHIMIZU, Hatsushi
Kantetsu Tsukuba Bldg. 6F
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JAPON

Date of mailing (day/month/year) 31 August 2006 (31.08.2006)	
Applicant's or agent's file reference M3-A0305P	IMPORTANT NOTIFICATION
International application No. PCT/JP2005/000567	International filing date (day/month/year) 19 January 2005 (19.01.2005)
Applicant MEDICAL AND BIOLOGICAL LABORATORIES CO., LTD. et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference M3-A0305P	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2005/000567	International filing date (<i>day/month/year</i>) 19 January 2005 (19.01.2005)	Priority date (<i>day/month/year</i>) 19 January 2004 (19.01.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MEDICAL AND BIOLOGICAL LABORATORIES CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report
22 August 2006 (22.08.2006)

Authorized officer

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PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

M3-A0305P

FOR FURTHER ACTION

... See paragraph 2 below

International application No.

PCT/JP2005/000567

International filing date (day/month/year)

19.01.2005

Priority date (day/month/year)

19.01.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

MEDICAL AND BIOLOGICAL LABORATORIES CO., LTD.

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000567

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☒

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000567

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 1-7, 10-13 and 16 (respectively partial)

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-7, 10-13 and 16 (respectively partial)
are so unclear that no meaningful opinion could be formed (*specify*):

- ☒ the claims, or said claims Nos. 1-7, 10-13 and 16 (respectively partial) are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 1-7, 10-13 and 16 (respectively partial)

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/000567

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>6-19</u>	YES
	Claims	<u>1-5</u>	NO
Inventive step (IS)	Claims	<u>6-19</u>	YES
	Claims	<u>1-5</u>	NO
Industrial applicability (IA)	Claims	<u>1-19</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

Document 1: "Enhanced levels of CD154 (CD40 ligand) on platelets in patients with chronic heart failure," (C. Stumpf et al.), Eur. J. Heart Fail, 2003, 5(5), pages 629-637

Claims 1-5

Document 1 describes an anti-CD61 antibody (see Abstract). Said antibody is considered to the same as the substance relating to the above claims. So, the subject matter of claims 1-5 do not appear to be novel or to involve an inventive step in view of document 1.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/000567

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-6 and 16

What "substance or its derivative" relating to claims 1-6 are concretely like is unknown. So, claims 1-6 are not considered to be described clearly.

As a "substance and its derivative," the substance "having a CD61 protein bonding ability and an effect of inhibiting inflammatory cytokine production" in actually presented in working examples etc. are only a #33 antibody, an anti-CD61 antibody and a F(ab')₂ transforming #33 antibody. Except these, what substances fit the above prescription is unknown. Moreover, a person skilled in the art is required to do excessive trial and error when actually verifying that a substance "has a CD61 protein bonding ability and an effect of inhibiting inflammatory cytokine production." So, the subject matters of claims 1-6 and 16 appear to be neither supported by the specification nor disclosed so clearly and sufficiently as to be performed by an expert in the relevant technical field.

In addition, an investigation is not carried out about such an invention whose claims are not clearly described, whose specification is not sufficiently supported and which is not clearly and sufficiently disclosed in the specification.

Claims 1-6 and 16

What structure in the concrete "derivative" relating to the above claims has is unknown. So, the subject matters of claims 1-6 and 16 do not appear to be clearly described.

Moreover, as for the "derivative," what substances have "a CD61 protein bonding ability and an effect of inhibiting inflammatory cytokine production" is unknown. A person skilled in the art is required to do excessive trial and error when obtaining such substances. So, the subject matters of claims 1-6 and 16 are neither sufficiently supported by the specification nor disclosed so clearly and sufficiently as to be performed by an expert in the relevant technical field.

In addition, an investigation is not carried out about such an invention whose claims are not clearly described, whose specification is not sufficiently supported and which is not clearly and sufficiently disclosed in the specification.

Claims 7 and 10-13

Claim 7 describes an anti-CD61 antibody coded by "a DNA hybridizing on a stringent condition" and "a DNA coding an amino-acid array in which one or a plurality of amino acids are lacked, added, inserted and/or substituted" in claim 7. Claims 10-13 describe an anti-CD61 antibody whose heavy or light chain is composed of polypeptide containing an amino-acid array in which "one or a plurality of amino acids are lacked, added, inserted and/or substituted." There is a low probability that such varied anti-CD61 antibodies as above have the same activation as an original antibody has. So, what structure in the concrete a DNA or polypeptide corresponding to the DNA or polypeptide regarding to the above claims has is unknown. A person skilled in the art is required to do excessive trial and error when obtaining such a DNA or polypeptide. Therefore, claims 7 and 10-13 do not appear to be clearly described and the subject matters of these claims are neither supported sufficiently by the specification nor disclosed so clearly and sufficiently as to be performed by an expert in the relevant technical field.

In addition, an investigation is not carried out about such an invention whose claims are not clearly described, whose specification is not sufficiently supported and which is not clearly and sufficiently disclosed in the specification.